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# MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036

Telephone: (202)-223-1424/1747 · Fax: (202)-223-0141 · E-MAIL: [Mandava@compuserve.com](mailto:Mandava@compuserve.com)

## HAND DELIVERED

November 7, 2008

Tom Myers  
Chemical Review Manager  
Special Review and Reregistration Division (7502P)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

SUBJECT: Response to Data Call-In Notice for Generic Data  
Generic Chemical Name: Streptomycin  
Registrant Name: Repar Corporation  
EPA Company Name: 69361

Dear Mr. Myers:

In response to Data Call-In (DCI) Notice for streptomycin, Repar Corporation ("Repar") is submitting the following information:

- 1) Completed and signed Data Call-In Response Form
- 2) Completed and signed Requirements Status and Registrant's Response Form
- 3) Completed and signed Cost Share Form (EPA Form 8570-32)

Please be advised that Repar is not submitting the Certification with Respect to Data Compensation Requirements (EPA Form 8570-31) because Repar is not relying on others' generic data for Streptomycin under the subject DCI Notice. To Repar's knowledge, no other company owns the data or submitted to EPA the generic data required under the subject DCI Notice.

Re. REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

### 1. Low Volume Exemption Request (Option 8)

Repar requests the Agency to waive all the environmental fate studies as noted below:

<u>Guideline</u>	<u>Study Title</u>
835.1230	Sediment and soil adsorption /desorption for parent and degradates
835.2120	Hydrolysis of parent and degradates as a function of pH at 25°C
835.2240	Direct photolysis rate of parent and degradates in water
835.4100	Aerobic soil metabolism

received  
11/13/08  
2

The rationale for data waivers for the above studies under low volume exemption (LVE), as described in detail in Attachment 1, is the following:

- 1) Streptomycin is a low volume use chemical and the exposure is considered to be very low. Therefore, the risk is negligible.
- 2) Since streptomycin is a naturally occurring substance and has a proven track record for safety (see RED), it is considered to be a reduced risk pesticide.
- 3) Streptomycin is listed in the USDA's National Organic Program (NOP) for organic crop production.

Although the environmental fate data were waived when RED was issued, the Agency imposed the above cited environmental fate data during TRED phase in order to address the resistance-related concerns. The registrant notes that there is an ample published data in the open literature that would adequately address the environmental concerns. (The registrant believes that, from the literature data, the Agency can derive the end-points for hydrolysis, and adsorption/desorption and soil metabolism studies for making the environmental assessment.)

In registrant's opinion, there is no economic incentive for conducting the costly environmental fate studies (even under the cost sharing program among the five generic chemical companies). Furthermore, these costly studies are unlikely to contribute any additional information to the existing published data for assessing the environmental safety of a low volume use chemical. If the Agency grants the LVE for streptomycin, the registrant believes that considerable resources will be saved to EPA and to the registrants.

## **2. Other Options if LVE is not granted**

### **2.1. Environmental Fate Studies**

In the event that the Agency does not grant the LVE for streptomycin, the registrant will participate in the cost sharing program only for **TWO** environmental fate studies and therefore Repar chooses **OPTION 3** for the following studies:

835.1230	Sediment and soil adsorption /desorption for parent and degradates
835.2240	Direct photolysis rate of parent and degradates in water

Repar will not conduct the following two environmental fate studies and instead it will amend the label by deleting certain uses (see Footnotes 1 and 3 for Environmental Fate Data Requirements). For these two studies, Repar chooses **OPTION 7**.

835.2120	Hydrolysis of parent and degradates as a function of pH at 25°C
835.4100	Aerobic soil metabolism

2.2. Other Studies

Repar will conduct other studies (see below) and therefore it chooses **OPTION 3** on **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM**.

830.7050	UV/Visible absorption
810.1000	Overview, Definitions, and General Considerations

Repar will participate with other registrants in cost sharing program for the development of the following studies. Therefore, Repar is submitting a Completed and Signed Cost Share Form (EPA Form 8570-32) with this letter.

<u>Guideline</u>	<u>Study Title</u>
830.1230	Sediment and soil adsorption/desorption for parent and degradates
835.2240	Direct photolysis rate of parent and degradates in water
830.7050	UV/Visible absorption
810.1000	Overview, definitions and general considerations

Since the **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** does not provide adequate space for indicating the options (alternatives - either Option 8 or Option 3 and Option 7), we request you to consider this letter for full details.

We have submitted additional information in Attachment 1 in support of Repar's response to Data Call-in Notice for Streptomycin.

If there are further questions, please contact us at (202) 223-1424.

Sincerely,



N. Bhushan Mandava, Ph.D.  
Agent for Repar Corporation

Attachment



United States Environmental Protection  
Agency Washington, D.C. 20460  
**DATA CALL-IN RESPONSE**

OMB Approval 2070-0107  
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address Repar Corporation c/o MANDAVA ASSOCIATES, LLC 1050 Connecticut Avenue, N.W., Ste 1000 Washington, D.C. 20036		2. Case # and Name 0169 Streptomycin Chemical # and Name 006310 Streptomycin sulfate		3. Date and Type of DCI and Number 16-Jul-2008 GENERIC ID # GDCI-006310-27845	
4. EPA Product Registration	5. I wish to cancel this product regis- tration volun- tarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
69361-8	NO	NO	YES	N.A.	N.A.
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <u>N. Bhushan Mandava</u> Agent				9. Date 11-07-08	
10. Name of Company Repar Corporation				11. Phone Number (202) 223-1424	

Green card date: 7/21/08

United States Environmental Protection  
Agency Washington, D.C. 20460OMB Approval 2070-0107  
OMB Approval 2070-0057

## REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary.

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
835.1230	<u>Environmental Fate Data Requirements (Conventional Chemical)</u> Sediment and soil absorption/desorption for parent and degradates					A, C	TGAI or PAIRA	12 (7/21/08)	Option 3
835.2120	Hydrolysis of parent and degradates as a function of pH at 25 C (1)					A, C	TGAI or PAIRA	12 (7/21/08)	Option 7-3
835.2240	Direct photolysis rate of parent and degradates in water (2)					A, C	TGAI or PAIRA	12 (7/21/08)	Option 3
835.4100	Aerobic soil metabolism (3)					A, C	TGAI or PAIRA	24 (7/21/08)	Option 7-3
830.7050	<u>Product Chemistry Data Requirements (Conventional Chemical)</u> UV/Visible absorption					A, C	TGAI/PAI	8 (7/21/08) 7/31/08	Option 3
810.1000	Overview, Definitions, and General Considerations					A, C		12 (7/21/08)	Option 3
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law Signature and Title of Company's Authorized Representative <u>N. Bhushan Mandava</u> Agent							11. Date 11-07-08		
12. Name of Company Repar Corporation <u>Bhushan C. Mandava - Com</u>							13. Phone Number (202) 223-1424		

United States Environmental Protection  
Agency Washington, D.C. 20460

**LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE**

Case # and Name: 0169, Streptomycin

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
71185	GEO LOGIC CORPORATION		PO Box 3091	TEQUESTA	FL 33469
69361	REPAR CORP	MANDAVA ASSOCIATES, LLC	1050 CONN. AVE., N.W., SUITE 1000	WASHINGTON	DC 20036
55146	NUFARM AMERICAS, INC.	NUFARM AMERICAS, INC.	4020 AERIAL CENTER PKWY., STE 101	MORRISVILLE	NC 27560
83558	ADAMA CELSIUS PROPERTY B.V., AMSTERDAM (NL)	MAKHTESHIM AGAN OF NORTH AMERICA, INC., D/B/A ADAMA	3120 HIGHWOODS BLVD., SUITE 100	RALEIGH	NC 27604